

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMB

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Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices  
Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on September 24, 2001, from 8:30 a.m. to 5 p.m.

*Location:* Hilton DC North—Gaithersburg, Salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD.

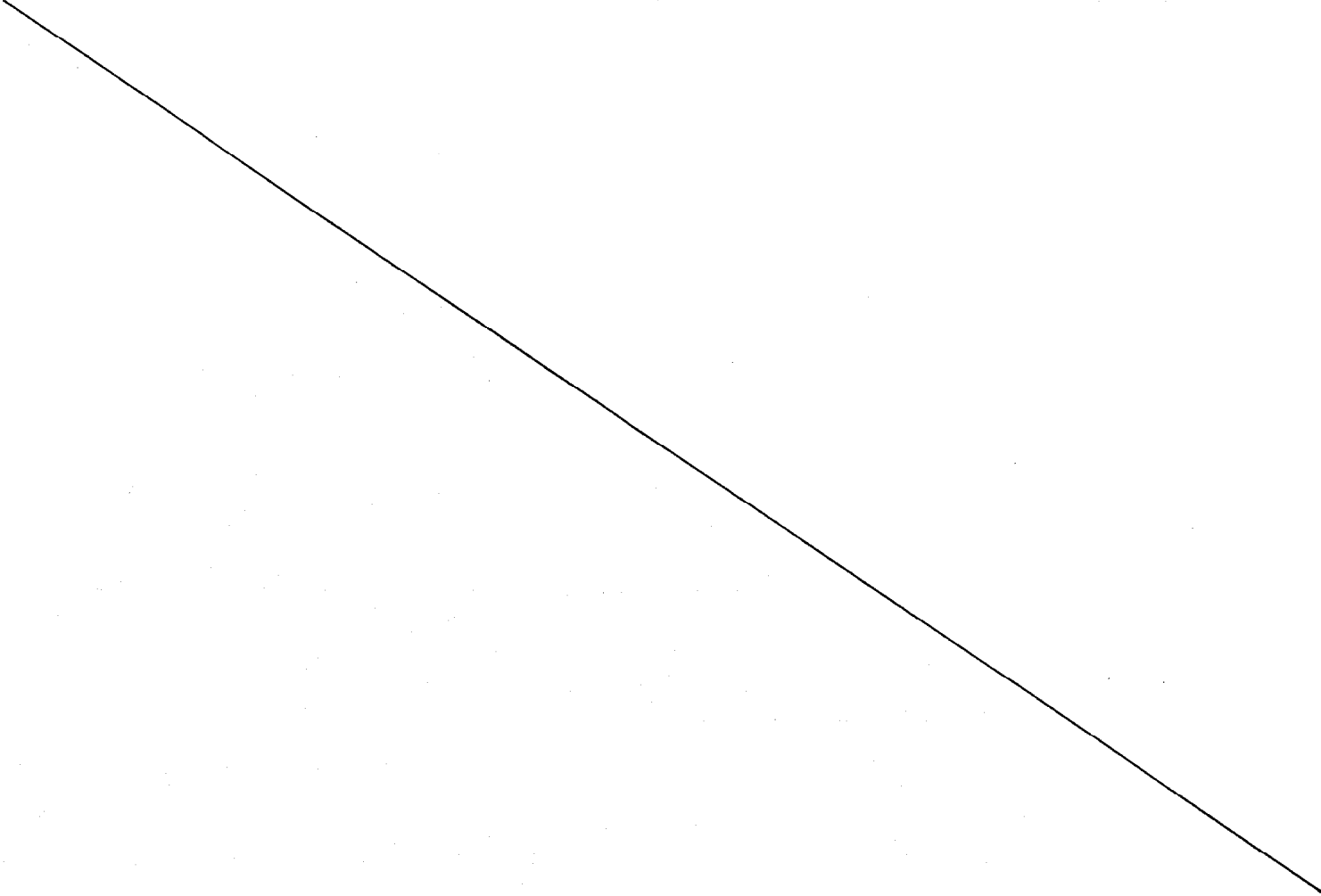
*Contact:* Veronica J. Calvin, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-1243, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12514. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* The committee will provide advice and recommendations on the types of data and/or labeling needed in premarket notification (510(k)) submissions for glucose test systems to address problems associated with using blood samples from alternate sites, such as the forearm, upper arm, thigh, calf, or base of the thumb. Background information, including the agenda and

questions for the committee, will be available to the public on September 21, 2001, on the Internet at <http://www.fda.gov/cdrh/panelmtg.html>.

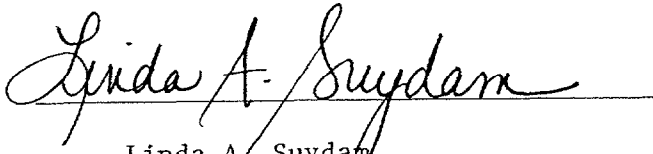
*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by September 12, 2001. Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12 noon and 3 p.m. and 3:30 p.m. on September 24, 2001. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 12, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).



Dated: 8/22/01

August 22, 2001.



Linda A. Suydam,  
Senior Associate Commissioner.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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